

AD _____

GRANT NUMBER DAMD17-94-J-4360

TITLE: Facility Inreach Strategy to Promote Annual Mammography

PRINCIPAL INVESTIGATOR: Joni A. Mayer, Ph.D.

CONTRACTING ORGANIZATION: San Diego State University Foundation
San Diego, California 92182-1900

REPORT DATE: October 1997

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

DRUG QUALITY INSPECTED 4

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE October 1997	3. REPORT TYPE AND DATES COVERED Annual (1 Oct 96 - 30 Sep 97)	
4. TITLE AND SUBTITLE Facility Inreach Strategy to Promote Annual Mammography			5. FUNDING NUMBERS DAMD17-94-J-4360	
6. AUTHOR(S) Mayer, Joni, A., Ph.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) San Diego State University Foundation San Diego, California 92182-1900			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited			12b. CODE 19980212 063	
13. ABSTRACT (Maximum 200 words) Six mammography facilities were recruited by March, 1996. Physician recruitment was completed in June, 1996. In total, 82 physicians are participating; participation rates ranged from 35-67% across facilities. Subject recruitment was completed in April, 1997. Women approached to participate: a) had a participating physician, b) were 50-74 years, c) were asymptomatic, d) had no personal history of breast cancer, and e) spoke English or Spanish. Over the course of the 23 month recruitment period, 3,701 eligible women were approached and 1,971 (53%) of those consented to participate. Of the 1,971 consenting women, 108 women subsequently had positive mammograms and were excluded from the study, leaving 1,863 subjects. All subjects were interviewed by phone regarding knowledge, attitudes, and behaviors related to mammography. Overall, 1,818 telephone interviews were completed; interviewing concluded in September, 1997. The intervention is ongoing through April, 1998. To date, 1,182 women have been randomly assigned to groups and outcome data have been collected for 14 waves of subjects (n=1,038). Outcome data collection will be completed in June, 1998.				
14. SUBJECT TERMS Breast Cancer, Mammography, Adherence, Appointment Reminder, Screening Guidelines, Inreach, Humans, Clinical Trials, Intervention, Physician Advice			15. NUMBER OF PAGES 45	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

___ Where copyrighted material is quoted, permission has been obtained to use such material.

___ Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

___ Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

___ In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

JM For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

___ In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

___ In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

___ In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

John Thayer 9-25-97
SI - Signature Date

TABLE OF CONTENTS

	<i>Page</i>
I. FRONT COVER	1
II. REPORT DOCUMENTATION PAGE	2
III. FOREWORD	3
IV. TABLE OF CONTENTS	4
V. INTRODUCTION	6
Description of the Subject.....	6
Background of Previous Work	7
Purpose of the Present Work and Scope of the Research.....	8
VI. BODY	9
Experimental Methods	9
Overview of Project	9
Strategies to Enhance Participation	10
Study Facilities	10
Referring Physicians	12
Subjects	12
Inclusion of Minorities	14
Intervention Procedures	14
Measures and Assessment Procedures	15
Pre-Intervention Survey	15
Measurement of Outcome	17
Other Measures	17
Statistical Analysis	18
Results	18
Physician Recruitment	18
Subject Recruitment	19
Subject Attrition	21

	Survey Data.....	22
	Outcome Data	23
VII.	CONCLUSIONS	23
	Clarification of Sample Size Requirements	23
	Problems/Challenges Encountered and Solutions	23
VIII.	REFERENCES	25
IX.	APPENDICIES	27
	APPENDIX A.....	27
	APPENDIX B	29
	APPENDIX C	31

INTRODUCTION

Description of the Subject

Breast cancer is the most prevalent type of cancer and the second leading cause of cancer-related mortality in American women (1). In 1997, there will be an estimated 180,200 new cases among women in the U.S. and 43,900 breast cancer deaths (1). Although progress has been made in the medical treatment of breast cancer, early detection and treatment continue to be the best predictors of an improved prognosis (1;2). Mammography is clearly the most sensitive and specific method of early detection (3). Results from recent trials have shown a decrease in mortality by up to 33% in women aged 50 and older (4). Currently, the National Cancer Institute (NCI), the American Cancer Society (ACS), and other agencies recommend annual mammograms for women 50 and older.

As noted in a review of the literature published prior to the initiation of our study (5), results from surveys showed positive secular trends in rates of both "ever" mammograms and in mammograms in the past year. However, adherence to the screening guidelines that are needed to reduce breast cancer mortality continued to be low (6-11). In the four studies that examined the rates and correlates of interval adherence, the rates of "more than 1" mammogram for women 50+ were 23%, 34%, 45%, and 47% (8-11). In all studies, physician recommendation consistently predicted repeat screening.

Mammography screening at regular intervals involves an interplay between the primary (or referring) physician, the patient, and the mammography provider (12). Following the initial mammogram, the mammography provider has information about the patient, and is able to conduct inreach activities to increase return rates. Mammography facilities routinely use reminder strategies to encourage patients to return. In an urban area where numerous facilities are competing, increased return rates may be crucial to keep revenues up. A collaboration between these facilities and public health interventionists has the potential to serve both public health and business objectives. Moreover, the probability for institutionalizing an intervention is high if the program increases revenues for the facility.

At the time the present study began, only three studies (excluding a pilot study described in the following section) had evaluated facility-based strategies to increase mammography return rates. In one study (13), return rates for a reassuring letter, an anxiety-provoking letter, and a "standard" hospital reminder letter were 54%, 42%, and 38% (n.s.). Our research group conducted two studies at a hospital-based mammography center comparing the standard reminder letter with other interventions (14). In Study 1, mailed reminder and reminder-plus-incentive subjects had appointment completion rates of 36% and 32%, respectively (n.s.). In Study 2, mailed reminder and telephoned subjects had appointment completion rates of 44% and 48%, respectively (n.s.). In contrast, in a recent meta-analysis, mailed reminders were consistently useful in reducing

broken appointments (15). Reminder letters have been successful in promoting general mammography appointment adherence (16) and cervical screening appointment adherence (17,18) relative to no letters.

In sum, studies have shown that reminder letters can increase medical appointment compliance in general and cancer screening appointments specifically. However, in the area of mammography adherence, there is a lack of trials to evaluate reminder strategies using true control groups and focusing on interval adherence. Because of the importance of physician recommendation as a facilitator in mammography interval adherence, incorporating the physician's endorsement of screening in a reminder strategy appears warranted.

Background of Previous Work

Studies 1 and 2. Two intervention pilots were conducted at the same facility during December, 1991 to March 1992 to evaluate the effects of various strategies on return rates of asymptomatic women, having no history of breast cancer, aged 50+ (14). In Study 1, all 50+ patients seen at the facility in 1-91 (N=187) were randomly assigned to receive the usual facility reminder postcard or the postcard plus a voucher for a small gift (valued at \$2.00) the month of the return date. In Study 2, all patients seen at the facility in 2-91 (N=184) were randomly assigned to receive either the postcard or a telephone reminder. During the phone call, patients were given the opportunity to schedule their appointment. Appointment completion rates (i.e., scheduled and kept the appointment) were monitored for the target appointment month plus one additional month.

Within both studies, groups were comparable on age (mean=64). In Study 1, the reminder only and reminder plus incentive groups had return rates of 36% and 32%, respectively (n.s.). The results were not in the predicted direction. Only 10 of 96 coupons were returned. In Study 2, mailed reminder and telephoned reminder subjects had appointment completion rates of 44% and 48%, respectively (n.s.). Only 26% of the phoned subjects scheduled appointments at the time of the call. The added expense of the calls was not justified by the 4% increase in return rates. Given the emerging literature (9-11,19), we reasoned that a mailed prompting strategy that emphasized the primary care physician's recommendation for annual mammography would be more powerful than the standard mailed prompt without being prohibitively labor-intensive. There was also a need to systematically estimate the effects of no reminders on return rates. Consequently, a third intervention pilot was conducted.

Study 3. This intervention was the prototype for the intervention that will be evaluated in the present study (14). The facility, which had been in business for 6 years and was affiliated with a hospital, provided approximately 4,224 screening mammograms per year and worked with approximately 428 referring physicians. Prior to the study, physicians who were frequent referrers to this facility were asked for their consent for the facility to prompt their patients using their letterhead and randomly assign their patients to the intervention or control (delayed reminder) group. Of the 19 physicians who were

contacted, 15 (79%) agreed to participate. Within each physician, women aged 50+ without a breast cancer history who had been referred to this facility in November, 1991 and who had a negative screening mammogram were randomly assigned to the two groups, resulting in 32 women in the intervention group and 31 women in the control group. Reminders stating the physician's endorsement of annual screening were mailed to intervention subjects the last week of October, 1992. The facility based reminders that the facility routinely uses were withheld from all subjects; control subjects received them at the end of the study. Return rates during November and December of 1992 were monitored.

The median ages of subjects in the reminder and control groups were 61 and 62, respectively (Range=52-91). Ninety percent were aged 52 to 75. The outcome was encouraging: return rates for the reminder and control groups were 47% and 19%, respectively, $\chi^2(1) = 5.29, p < .05$. This was a relative increase of 147%. The chart review 14 month return rate for this facility, which used a "standard" reminder, was 26%. With the exception of two subjects who were both in the reminder group, all subjects who returned did so during November. The success of the intervention in this controlled pilot study warranted a larger trial.

Purpose of the Present Work and Scope of the Research

The primary purpose of this study is to increase annual return rates for screening mammography among asymptomatic women aged 50 and older. Specific project objectives include:

- a. To develop an intervention aimed at promoting return mammogram adherence within 12-14 months following the last mammogram. The intervention will consist of an appointment reminder letter mailed by the mammography facility but originating from the referring physician; the physician will endorse the importance of annual screening for the patient.
- b. To refine and standardize a comparison reminder letter. Typically used by mammography providers, this letter will originate from the facility to encourage return appointments.
- c. To implement and monitor the proposed interventions at six mammography facilities in San Diego, California that have adequate patient volume to meet sample size requirements. Cooperation of primary care providers that refer patients to these facilities will be obtained.
- d. To evaluate the effectiveness of the primary care physician's letter in increasing return mammogram adherence relative to the "standard" facility letter and to no intervention. The study will use a three group, randomized design with 1,560 subjects randomized

from within referring physician within mammography facility. We hypothesize that the physician letter will produce significantly higher adherence than the standard letter, and that the standard letter will produce significantly higher adherence than no letter.

A secondary purpose is to increase the understanding of the factors that influence interval adherence to mammography. Specific objectives relevant to this goal are:

- a. To assess via a phone interview selected demographic, psychosocial, health-related, health services, and mammography-experience related variables within approximately 4-8 weeks after a screening mammogram.
- b. To evaluate prospectively relationships between these variables and subsequent mammogram adherence, controlling for study condition.

BODY

Experimental Methods

Overview of Project

The study is using a randomized three-group design to compare the effects of two interventions and a control condition on annual return rates to mammography facilities for screening mammograms by women who are 50-74 years. The treatments include a) delayed appointment reminder (control), b) "standard" reminder -- appointment reminder from the facility that provided last year's mammogram, and c) physician endorsement reminder -- appointment reminder to be distributed by the facility (with physician's permission) with physician's prompt to patient to have an annual mammogram at the facility. If the physician endorsement reminder is effective, inclusion of the standard reminder group will allow us to draw conclusions about why (i.e., is it the general reminder element or the physician's endorsement that is important?)

Study procedures are as follows for subjects in a given wave: a) potential subjects are approached by the project at or around the time of the study entry mammogram; b) subject consent forms are completed and collected; c) verification is made that the entry mammogram had negative results; d) the interview is conducted within approximately 8 weeks of the study entry mammogram; e) approximately eleven months after being recruited, subjects are randomly assigned to groups; f) for subjects in the standard reminder and physician endorsement reminder groups, reminder letters are mailed the day before the first day of the targeted appointment month; g) staff monitors facility appointment records to evaluate return rates of subjects within 60 days (of day 1) of the targeted appointment month; h) reminder letters are mailed to control group subjects on the last day of the 60 day monitoring period; i) staff monitors facility

appointment records to evaluate return rates of subjects within 6 months (of day 1) of the targeted appointment month.

Measurement procedures consist of a) a 43 item telephone interview within approximately 4-8 weeks following the study entry mammogram to obtain information on demographic characteristics, mammography history, perceptions of the mammography experience, selected health history, knowledge of mammography guidelines, health beliefs specific to breast cancer and mammography, intentions to have a subsequent annual mammogram, self-efficacy for obtaining annual mammography, and access to medical care; b) monitoring facility appointment records to evaluate return rates of subjects within 60 days (of day 1) of the targeted appointment month; and c) monitoring facility appointment records to evaluate return rates of subjects within 6 months (of day 1) of the targeted appointment month.

We originally planned to conduct the study at four mammography facility sites (called "original sites"). After several months of subject recruitment at the original sites, we determined that we would not be able to reach the required sample size and decided to recruit two additional facilities. Two additional facilities were recruited during the grant year 1995-1996. The study is currently conducted at six mammography facilities in San Diego County. Random assignment of subjects to groups occurs within each facility and each referring physician. In order to achieve the final sample size of 1,560 subjects (520 per group), subject recruitment was extended through April, 1997. A total of 1,863 subjects were recruited (see Problems/Challenges section). The interviews and intervention are implemented in a staggered manner, with each lasting approximately 23 months (with overlap). The project is expected to be completed in 4 years in three phases: I. start-up activities, II. assessment and intervention procedures, and III. analysis and report preparation.

Strategies to Enhance Participation

The success of the project is dependent on adequate levels of participation by facilities, referring physicians, and subjects. Moreover, high response rates of each enhances the generalizability of the findings. Consequently, strategies for encouraging participation at each level were used. The research team includes a general practitioner, Linda Hill, M.D., M.P.H., who has provided consultation on the intervention from the referring physician's and patient's perspective and a radiologist, Charles Lee, M.D., J.D., who has consulted on quality assurance of mammography and other facility-related issues. The input of these consultants has helped assure that the intervention is acceptable to patients, referring physicians, and mammography providers.

Study Facilities

Inclusion criteria for sites were: a) patient volume can accommodate approximately one-sixth of the sample; b) computerized or manual record keeping system appears accurate and efficient; c) personnel at site agree to follow study protocol (e.g., delay

reminders for control group); d) facility is certified by the California Department of Health Services (CDHS) Radiologic Health Branch, is accredited by the American College of Radiology (ACR), and the Food and Drug Administration (FDA) e) facility uses a fee-for-service model; and f) facility has been in business for at least one year prior to the study's onset.

Generally, facilities are very interested in improving patient services, enhancing relationships with referring physicians, and increasing their revenues. They were told that these are three potential benefits of participating in the study via the introductory packet we mailed. Initially, project staff sent facility directors a packet containing the following: an introductory cover letter, pilot study results, a sample of the physician-endorsed reminder letter, and a chart stating the responsibilities of participating facilities and the project staff (timeline for all activities included). Next, phone calls were placed and face to face meetings were held.

We completed recruitment of the four original sites in January, 1995. South Bay Radiology is located in the southern portion of the county (Chula Vista), has a high proportion of Latinas who primarily speak Spanish (approximately 50% of patient population), and performs 30-35 screening mammograms a day. The Alvarado Breast Center is located in central San Diego county, has a Caucasian, middle class patient population, and performs 15-20 screening mammograms a day. The UCSD Center for Women's Health is also located in central San Diego County, has a diverse patient population, and performs 10-15 screening mammograms a day. Our fourth original site, the Lybrand Mammography and Education Center at Scripps Memorial Hospital, is located in northern San Diego county, has a primarily mid-upper income Caucasian patient population and performs 10-15 screening mammograms a day.

The second phase of facility recruitment was completed in March, 1996. Mercy Hospital Women's Imaging Center is located in central San Diego County, has a diverse patient population, and performs 10 screening mammograms a day. Tri-City Outpatient Imaging Center is located in the northwestern part of the county, has a primarily middle class patient population, and performs 20-30 screening mammograms a day.

Initial recruitment and continued participation by facilities has been assisted by minimizing the burden on facility staff for data monitoring and intervention procedures. A project staff person is responsible to each facility and in frequent contact to insure this, and an ongoing, problem-solving approach is used when complications arise. All procedures that involve the facility's assistance (e.g., sample selection, recruitment, intervention implementation) are as efficient as possible and are coordinated with the facility's schedule. An initial annual meeting was held at each of the study facilities as a forum for facility and project staffs to discuss study progress and share ideas for streamlining study procedures. Initial annual meetings were held in 1995-1996. A second set of annual meetings were held between April and June, 1997 to discuss the completion of subject recruitment, intervention progress, and appreciation for facility cooperation.

Referring Physicians

Prior to the physician recruitment phase of the study, approximately 23 physicians were questioned to assess any concerns with the intervention procedures via one focus group and one conference exhibit (the conference was directed towards primary care physicians). The physicians who provided us with feedback did not have reservations about study procedures, and almost unanimously approved of our physician-endorsed reminder letter, commenting that it was short and to the point. Pilot study physicians were also contacted for feedback. Six physicians responded and all stated that their experience was positive and that they would participate again.

In obtaining the cooperation of referring physicians, facility staff has assisted project staff. Facility staff identified 23-31 of the most frequently referring physicians to their facility. Project staff sent a packet containing the following: an introductory cover letter, letter of support from the facility medical director, pilot study results, a sample of the physician-endorsed reminder letter, and a chart stating the responsibilities of participating physicians and the project staff. In each packet was a self-addressed stamped envelope and form to be signed indicating the physician's participation. Follow-up calls were made until a response from each physician was obtained.

Physicians were encouraged not to modify their patient recall or referral patterns during the course of the study, nor to discuss the study with their patients. They were told they would be providing a blanket consent that potentially covers any of their referred patients who meet the other inclusion criteria. During physician recruitment, we reassured physicians that the control group will receive a reminder delayed by only 2 months. After a physician was recruited, project staff acquired the physician's stationery in an organized manner. During the subject recruitment phase (June 1995 - April 1997) physicians were sent a list of their patients participating in the study every few months. At the end of subject recruitment a comprehensive list of patients recruited were sent to each physician. Physicians will receive copies of the letters that were sent to patients in the physician endorsement reminder group at the end of the intervention phase. Physician recruitment was completed in June, 1996.

Subjects

Subjects were recruited in monthly waves over a 23-month period. Inclusion criteria were: a) age 50-74 (at the time of entry mammogram); b) no history of breast cancer; c) had routine screening mammogram at facility during the course of the study with negative test results; d) referring physician for entry mammogram agreed to the intervention protocol; e) consented to participate; and f) spoke either English or Spanish. Criterion c made the assumption that the woman was asymptomatic. Ongoing studies in progress in San Diego that may confound results of the present study have been determined. Subjects who are participating in the clinical arms of the Women's Health Initiative, determined by conversations with the investigators of the study, are excluded from the present study.

Prior to starting subject recruitment four focus groups were conducted with: African American women, Filipino/Caucasian women, Latinas, and Caucasian women. Questions were regarding telephone interview questions, the intervention letter, and subject recruitment strategies. Modifications to the telephone interview were made as a direct result of the feedback we received. For example, women objected to a series of questions regarding reasons for and timing of their three most recent mammograms. In the present version of the telephone interview, women are only asked about one of their prior mammograms. We were told repeatedly to keep the interview as short as possible. Another important finding was that women were split regarding preferences for introduction to the study by mailings versus in person - thus we attempted to reach all potential subjects by letter and phone before their mammography appointments. During the Latina focus group, wording/translations for medical terms like breast lump, clinical breast exam, and breast self-exam were clarified.

Participation rates of women in the study were maximized by: a) incorporating the recruitment and consent procedures into the mammography appointment and providing comprehensive training for the facility staff; b) both before and if necessary, after, the mammography appointment we contacted women by phone and/or mail to explain the project, c) employing mature, sensitive female interviewers who received comprehensive training, d) pilot testing the survey instrument and script for clarity, sensitivity, and duration and making necessary refinements, e) assuring confidentiality of responses, and f) for Latinas who prefer Spanish, providing Spanish language materials and a bilingual interviewer.

Subjects were recruited and written consent obtained near the time of the initial (entry) mammogram. Prior to this appointment, the appointment schedule containing information about inclusion criteria (e.g., physician consents, age, no breast cancer history) was highlighted. Research assistants attempted to reach all eligible subjects by phone before their appointments to explain the project. At three facilities (UCSD, Lybrand, Tri-City) we had access to eligible women's addresses; packets (containing an introductory letter and consent forms) were mailed in addition to the phone calls. Every afternoon a list of eligible subjects due for mammograms the next day was faxed to each facility. Two times a week research assistants determined which women were eligible but did not fill out consent forms; these women were re-contacted by phone and if still willing to participate, were mailed another consent packet.

The facility receptionists and mammography technologists received training by project staff to: a) briefly describe the study to the potential subject before or after the appointment, b) encourage the patient to read a brief description of the project (available in Spanish and English), c) provide the consent form (Spanish and English) and address any questions or concerns, and d) obtain written consent and provide a copy of the form to the patient. Although the test results for the mammogram were not available at the appointment, obtaining consent at that time maximized participation rates and was efficient from a recruitment perspective. Patients whose test results subsequently were found to be positive or inconclusive were excluded as subjects. Women were included in

the study if the interpreting radiologist recommended the next screening in one year. Potential subjects also were provided a self-addressed stamped envelope in case they preferred to read the information at home. Facility staffs' rates of recruitment and recruitment style were monitored by staff and feedback was given, as appropriate.

Subjects consented to participate in the study as a whole including a) the phone survey, b) random assignment to study conditions, and c) monitoring of mammography adherence. Women who refused survey participation at the time of the interview were dropped as subjects. One month prior to the targeted appointment month for a given wave, subjects in the wave (within referring physician within facility) are randomly assigned to one of the three study groups.

Inclusion of Minorities

Because language may be a barrier to participation in the study for San Diego's largest ethnic minority group, Latinos, two subject recruiters and two phone interviewers were bilingual in English and Spanish. The explanatory letter, consent form, and survey were translated into Spanish and Spanish-speaking women who were contacted for the survey had the choice of being interviewed in Spanish or English. Additionally, subjects who indicated a preference for Spanish in the interview received/will receive their intervention reminder letters in Spanish. Women who speak neither English nor Spanish were excluded as subjects.

Intervention Procedures

The intervention is implemented in monthly waves; the first wave of subjects were due for their targeted mammograms in June, 1996. All subjects in a wave received their study entry mammogram during the same calendar month. In order to simplify the mailing and monitoring procedures, the following occurs: a) the month of the subject's entry appointment is the designated month of the targeted appointment, irrespective of what day of the month it occurred; b) reminders are timed to arrive on or about day 1 of the targeted appointment month; c) the primary interval in which adherence is assessed for all subjects is 60 days, beginning with day 1 of the designated appointment month; and d) for secondary analysis, facility appointment records are monitored for an additional 4 months (6 months from day 1 of the targeted appointment month) for subject returns. The uniform mailing date for each wave dictates the uniform outcome monitoring period for each wave. The procedures for each study group are detailed below.

Group 1. The control group (within each facility and wave) receives no reminder during the outcome monitoring period for that wave. However, after the interval, they receive the "standard" (Group 2) reminder.

Group 2. These subjects receive the standard reminder on the facility letterhead prior to the targeted appointment month, as described above. All participating facilities

reached consensus on the wording of the standard facility reminder letter. The letter a) states that it has been a year since the last mammogram, b) encourages the patient to call her physician to schedule a clinical breast exam and obtain a mammography referral c) encourages the patient to call for a mammography appointment, and d) provides the facility's name, address, and phone number. A sample of the standard facility reminder is attached (Appendix A).

Group 3. These subjects receive the "physician endorsement" reminder letter on the referring physician's letterhead with his/her signature prior to the appointment month. In most cases the project purchased signature stamps to facilitate the timely mailings of the letters (some physicians decided to sign the letters). The content is the same as the standard reminder letter; the main difference is that the letter is from the physician rather than the facility. A sample of the physician endorsement reminder letter is also attached (Appendix B).

Project staff collected samples of the reminder letters used by the participating facilities as well as reminder letters used in similar studies. These samples were considered when drafting the final version of the reminder letters.

Measures and Assessment Procedures

The primary sources of data in the proposed study are patient self-report (i.e., the pre-intervention survey) and archival records maintained by the facilities (i.e., patient appointment data for measuring outcome). The measures are described in detail in the following sections.

Pre-intervention Survey

Purpose and content. A telephone interview was conducted with subjects to obtain data for describing the sample and for developing models to predict subsequent mammography adherence. The 43-item survey is attached (Appendix C). The items included:

- demographics: birthdate, education, ethnicity (and language preference, if Latina), marital status, employment status, income;
- provider variables: regular source of medical care, type of practice, is referring physician regular physician, specialty of referring physician;
- insurance coverage: type(s) of coverage;
- breast health history: previous breast complaint, previous breast cancer (exclude), previous biopsy, family history;
- screening history: total number of mammograms, dates of mammograms, reason for mammogram (diagnostic vs. screening), test results (if entry mammogram was diagnostic or had non-negative results, exclude), perceived screening pattern (e.g., sporadically, regularly-not annually, annually), perceived barriers (if not annually),

perceived facilitators (if annually), ever had CBE, date of last CBE, reason for last CBE, perform BSE, BSE frequency;

- knowledge/beliefs: ACS mammography guideline for 50+, odds of any woman getting breast cancer, odds of subject getting it, age-related risk;
- intentions to have mammogram next year: likelihood in general, likelihood if doctor recommends;
- expectations for having mammogram next year: confidence in being able to schedule and complete the appointment (i.e., self-efficacy), confidence that annual screening will improve survival (i.e., outcome expectation);
- recent mammography experience: general satisfaction with experience, level of discomfort during compression.

Although women with a history of breast cancer or a non-negative study-entry mammogram were excluded based on facility records, items assessing these criteria were included in the survey as a safety measure. Facility records were used to generate basic demographic data for survey nonresponders (e.g., age). Additionally, all women who declined to participate during the recruitment call or telephone interview were asked to answer seven questions regarding demographics and reason(s) for not participating.

Information regarding the study inclusion mammogram was obtained from facility logs or records. History of mammograms prior to this relied on self-report. Self-report of mammography was found to be highly accurate in one study (20) and fairly accurate but overestimating the recency of the exam (i.e., exam was less recent than reported) in another study (21). Previous interval adherence was assessed both by asking numbers and dates of exams and by asking the subject to describe her pattern. The intervention outcome does not rely on self-report.

Subcontract for Telephone Interviews. We researched six research firms located in San Diego County and asked about their: specializations, interviewer selection process and training, quality control measures, data handling, cost, and references. After conducting informational interviews over the phone, we visited two of the firms. We determined that each firm had more resources to ensure the quality of the interviews than we would at our office and could conduct the interviews at a lower cost than that originally budgeted.

We chose to work with Luth Research, a firm with over 20 years of experience. Luth has a 50 line WATS phone facility supervised by up to three managers at a time. One supervisor walks around the room and listens to interviews in progress and one listens to interviews in progress and has the ability to edit the interview if he/she detects an interviewer error (unknown to the interviewee). Via modem, we had the ability to "listen" to interview in progress as well. Luth Research uses Query software for their Computer-Assisted Telephone Interview (CATI) system. The CATI system guides

interviewers through survey questions and allows them to enter data as women answer questions. The quality and efficiency of Luth's work for the project were excellent.

Procedures. For each subject at each site, the research assistants (R.A.s) generated a telephone interview cover sheet with a woman's phone number and most convenient time to call. Subjects were phoned at the time they specified as most convenient. A minimum of 20 attempts were made to contact each woman whose phone number appeared to be current, and attempts were made to update old numbers. If a woman refused to participate in or complete the interview once it began, she was thanked politely; no coercion was used.

The interviewer introduced herself and verified language preference and personal breast cancer history. After the introduction, the interviewer proceeded with the 20-minute interview. The interviewer entered information into the computer as each question was answered, clarifying questions as needed, using the CATI system. Interviewers kept records of completed calls, refusals, and call backs on telephone interview cover sheets provided by the project.

Measurement of Outcome

The dependent variable, mammography adherence, is assessed by the R.A.s from appointment records maintained at each facility. The time frame monitored (for each wave) is 60 days, beginning on day 1 of the target appointment month. (Subjects in Groups 2 and 3 will have received their reminder letters immediately prior to this date). Appointment records also are used to determine if any subjects schedule an appointment prior to intervention for either a screening or diagnostic mammogram; these subjects' data are deleted from the analysis. Adherence is coded dichotomously (yes, no) and requires that the appointment be completed (i.e., both scheduled and kept) during the 60-day interval. Additionally, records are monitored to determine whether subjects return for a mammogram within 6 months of the first day of the targeted appointment month.

R.A.s make monthly visits to the facilities during the adherence monitoring phase to obtain appointment data on an ongoing basis. Facility staff have agreed in advance to comply with the study protocol, including record-keeping procedures, but will be provided feedback from project staff if needed in order to maintain the quality of the data.

Other Measures

Process data include: a) the number of facilities that were approached to reach the quota (completed), b) cooperation rates of referring physicians (completed), c) survey response rates (completed), d) perceptions of facility staff about the intervention procedures (in progress), e) perceptions of cooperating referring physicians about the intervention (in progress), f) use of systematic reminder strategies (in addition to project's) by physicians (in progress), and g) study participation rates by subjects

(completed). Additionally, we will note any potential relevant historical events that occur during the study that may influence screening rates.

Statistical Analysis

The primary hypothesis is that the physician endorsement letter will yield the highest adherence rate, followed by the standard letter, and no letter will yield the lowest rate. In addition to the analyses to evaluate this hypothesis, secondary analyses will examine relationships between baseline demographic, psychosocial, health-related, health services, and mammography-experience related variables and subsequent mammogram adherence, controlling for study condition.

First, selected baseline variables will be compared across the three groups to assess comparability. Chi-square tests for categorical variables and one-way analysis of variance for continuous variables will be used. Assuming comparability at baseline, a simple approach to assessing differences across adherence rates for all 1,560 subjects will be to construct a 3x2 contingency table for the two categorical variables, study condition and adherence outcome, and use a chi-square test. If the chi-square result is significant, pairwise contrasts will be performed to assess specific differences using a Bonferroni adjustment. The CATMOD procedure in the SAS statistical package will be employed.

A more comprehensive analysis which might yield greater precision will be to use multiple logistic regression (22) where the outcome variable is adherence/non-adherence to the mammogram. This procedure will allow identification of important baseline variables that may predict adherence, consistent with the secondary goal of the study and, if necessary, adjustment for baseline variables in assessing differences among the study conditions for the survey completers. We also will evaluate possible differences among the six radiology facilities and whether differences among study conditions may vary by facility. The latter analysis will be accomplished by incorporating condition by facility interaction terms into the logistic regression model. The logistic program (LR) in the BMDP statistical package will be used for the above analyses.

Results

Physician Recruitment

At each facility, 23-31 of the most frequently referring physicians were identified by mammography facility staff. Physician recruitment has been completed and physician participation rates varied across facilities: 67% at South Bay Radiology, 64% at UCSD Center for Women's Health, 48% at Lybrand Mammography and Education Center, 48% at Tri-City Medical Center, 45% at Alvarado Breast Center, and 35% at Mercy Hospital (see Table 1 below). Overall, 82 physicians are participating in the study from various specializations: 25 (30%) Obstetrics/Gynecology, 23 (28%) Internal Medicine, 16 (20%) Family Practice, 6 (7%) General Practice, and 12 (15%) from other specializations. The most common reasons physicians cited for not participating in the

study were: “too busy, no time” (even though we explained participation would require only 5-10 minutes total) and “not interested.”

Table 1
Referring Physician Recruitment Rates

Participation Status	Facility						
	South Bay	UCSD	Lybrand	Alvarado	Mercy	Tri-City	All Facilities
Participating	18 (67%)	16 (64%)	14 (48%)	14 (45%)	8 (35%)	12 (48%)	82 (51%)
Not Participating	9	9	15	17	15	13	78
Total Approached	27	25	29	31	23	25	160

Subject Recruitment

Subject recruitment rates varied at the six facilities: 76% of eligible women have consented at the Alvarado Breast Center, 62% at UCSD Center for Women’s Health, 54% at Lybrand Mammography and Education Center, 50% at Tri-City Outpatient Imaging Center, and 36% at Mercy Hospital. At South Bay Radiology, 44% of English-surname eligible women consented while 19% of Spanish-surname women consented for an overall rate of 31% (see Table 2 on the following page).

Over the course of the 23 month recruitment period, we identified and approached 3,701 eligible women. Of those women, 1,971 consented to participate in the study. Of the 1,971 consenting women, 108 women subsequently had positive mammograms and were excluded from the study, leaving 1,863 study subjects.

Table 2
Subject Recruitment by Facility

Facility	Participation Status		
	# Eligible ¹	# Consented	# Normal Mammograms (Study Subjects)
Facility 1: South Bay Radiology English Surname	399	175 (44%)	154
Facility 1: South Bay Radiology Spanish Surname	477	93 (19%)	81
Facility 2: UCSD Center for Women's Health	886	549 (62%)	525
Facility 3: Lybrand Mammography & Education Center	373	200 (54%)	187
Facility 4: Alvarado Breast Center	685	519 (76%)	485
Facility 5: Mercy Hospital	25	9 (36%)	7
Facility 6: Tri-City Medical Center	856	426 (50%)	424
All Facilities	3701	1971 (53%)	1,863

¹ Last year (in this column) we presented data regarding the number of women approached. However, some of these women subsequently were found to be ineligible. The eligibility data (all eligibles were recruited) provide more useful information when interpreting the participation rates.

Subject Attrition

Subject attrition rates varied among the six facilities: 19% of subjects recruited at South Bay Radiology were subsequently excluded, 16% at UCSD Center for Women's Health, 14% at the Alvarado Breast Center, 14% at Mercy Hospital, 9% at the Lybrand Mammography and Education Center, and 7% at the Tri-City Outpatient Imaging Center. Reasons for subject attrition are presented below in Table 3.

Table 3
Reasons for Subject Attrition

Reason	Percent of all subjects excluded from the study to date
Concurrently Enrolled in the Women's Health Initiative	44%
Returned to Facility Prior to Targeted Appointment Month	32%
Refused Telephone Interview	9%
Physician-Related Issues (e.g., physician retired)	7%
Wrong Age	4%
Other / Miscellaneous	3%
Deceased	1%

Survey Data

Overall, 1,818 telephone interviews were completed; interviewing concluded in September, 1997. Of the 1,863 subjects recruited, 18 (1%) women refused the survey and were excluded from the study. Interviewers were unable to reach 27 (1%) women; these subjects remain in the study. General information regarding subjects is summarized in Table 4 below.

Table 4
Characteristics of Sample

N=1,818	
<hr/>	
Age:	
Mean	60 years
Range	50-74 years
Family Income:	
0-\$20,000	18%
\$20,001-\$40,000	38%
\$40,000+	44%
Ethnicity:	
White, Caucasian	84%
Hispanic, Latina	8%
African American	3%
American Indian	<1%
Asian	2%
Pacific Islander	<1%
Other	2%
Education:	
0-12th grade	29%
Post high school	71%
Marital Status:	
Married	62%
Not married	38%
Insurance:	
Has insurance	95%
Does not have insurance	5%
Number of Mammograms:	
1-5	38%
6-10	40%
11-15	13%
16+	10%

Outcome Data

The intervention for the first wave of subjects was implemented in June, 1996. The projected date for the completion of data collection is June, 1998. Three hundred ninety-eight subjects have been randomly assigned to the control group, 393 to the standard facility reminder group, and 391 to the physician-endorsed reminder group. To date, we have collected outcome data for 14 waves of subjects (n=1,038). Our project statistician has requested that all outcome data be collected before any analysis is performed and results are reported.

CONCLUSIONS

Clarification of Sample Size Requirement

From the inception of the study, the final sample size required has been 1,560. The subject recruitment goal varied over time depending on the attrition rate at any given time.

Problems/Challenges Encountered and Solutions

1. Subject and Physician Attrition

As we completed additional waves of the intervention during Year 3, the subject attrition rate increased from 4% (reported in Year 2 annual report) to an average of approximately 15%. To account for the projected loss of 15% of subjects, we recruited 1,863 subjects (covers a 16% attrition rate) to ensure that outcome data would be collected for 1,560 subjects. Subject recruitment was prolonged as long as logistically and financially possible to account for the loss of subjects. As shown in Table 3, the 2 main reasons for the increase in attrition rates were: 1) subjects enrolled in both our study and the Women's Health Initiative (clinical arms of the study require women to have an annual mammogram); and 2) subjects returned for a mammogram before their targeted appointment month. The subject attrition rate was highest among facilities at South Bay Radiology (19%), particularly due to women enrolling in the Women's Health Initiative. Once the intervention waves were completed at that site (April, 1997) the overall attrition rate declined. Fortunately, subject attrition rates are currently lowest at Tri-City Outpatient Imaging Center, the site from which the majority of subjects yet to receive the intervention were recruited.

Another related project challenge encountered was the loss of 4 participating physicians who moved or retired. In one instance we recruited the physician who acquired the retiring physician's practice; all subjects were retained. In the other three instances, patients of the departing physicians were given a list from which they were instructed to choose a new physician; the list includes some of our participating physicians. If the women choose one of our participating physicians they are retained as

subjects. Unfortunately, most women do not select their new physician until they need to schedule a medical appointment. We are checking on a weekly basis to determine if these women designate a new physician. If more than one of these women choose the same physician, we will attempt to recruit that physician.

2. Latina Subjects

Despite our efforts, we were unable to recruit a subset of Latina subjects representative of the San Diego County female population 50-74 years (approximately 12%). Overall, 8% of our subjects self-identified as Latina. All project recruitment and intervention materials were translated into Spanish and bi-lingual phone recruiters were hired. Unfortunately, nearly all study eligible Latina women came from the South Bay Radiology site where subject recruitment was halted prematurely. In addition, the attrition rate among sites was highest at South Bay Radiology (19%). One of the primary reasons the Tri-City site was recruited was the potential for recruiting additional Latina subjects. We were able to recruit 29 Latina subjects from the Tri-City site. Because the facility is located 38 miles from our offices, in-person Latina recruitment was not feasible.

In conclusion, we are confident that we will be able to accomplish all of our study's aims, with the 12-month, no cost extension of our original timeline that was approved in the spring of 1997. Primary project activities remaining include completion of intervention implementation (April, 1998), outcome data collection (June, 1998), physician and facility surveying (Summer, 1998), and data analysis and report writing (Summer, 1998).

REFERENCES

1. American Cancer Society. (1997). Cancer Facts and Figures-1997. Atlanta: American Cancer Society.
2. National Cancer Institute. (1986). Cancer control objectives for the Nation: 1985-2000. P. Greenwald & E.J. Sondik (Eds.). NCI Monographs, NIH Publication No. 86-2880, Number 2.
3. Gohagan, J.K., Rodes, N.D., Blackwell, C.W., Darby, W.P., Herder, T., Pearson, D.K., Spitznagel, E.O., & Wallace, M.D. (1980). Individual and combined effectiveness of palpation, thermography, and mammography in breast cancer screening. Preventive Medicine, 9, 713-721.
4. Howard, J. (1987). Using mammography for cancer control: An unrealized potential. Ca - A Cancer Journal for Clinicians, 37, 33-48.
5. Rimer, B.K. (1992). Understanding the acceptance of mammography by women. Annals of Behavioral Medicine, 14, 197-203.
6. NCI Breast Cancer Screening Consortium. (1990). Screening mammography: A missed clinical opportunity? Journal of the American Medical Association, 264, 54-58.
7. Centers for Disease Control. (1990). Use of mammography - United States, 1990. Morbidity & Mortality Weekly Report, 39, 621-630.
8. Stomper, P.C., Kopans, D.B., Sadowsky, N.L., et al. (1988). Is mammography painful? A multicenter patient survey. Archives of Internal Medicine, 148, 521-524.
9. Howe, H.L. (1992). Repeat mammography among women over 50 years of age. American Journal of Preventive Medicine, 8, 182-185.
10. Lerman, C., Rimer, B., Trock, B., Balshem, A., & Engstrom, P.F. (1990). Factors associated with repeat adherence to breast cancer screening. Preventive Medicine, 19, 1-12.
11. Zapka, J.G., Stoddard, A., Maul, L., & Costanza, M.E. (1991). Interval adherence to mammography screening guidelines. Medical Care, 29, 697-707.
12. Costanza, M.E., D'Orsi, C.J., Greene, H.L., Gaw, V.P., Karellas, A., & Zapka, J.G. (1991). Feasibility of universal screening mammography. Archives of Internal Medicine, 151, 1851-1856.
13. Kendall, C., & Hailey, B.J. (in press). The relative effectiveness of three reminder letters on making and keeping mammogram appointments. Behavioral Medicine.
14. Mayer, J., Bartholomew, S., Clapp, E.J., & Elder, J. (1994). Facility-based inreach strategies to promote annual mammograms. American Journal of Preventive Medicine, 10, 353-355.
15. Macharia, W.M., Leon, G., Rowe, B.H., Stephenson, B.J., & Haynes, B. (1992). An overview of interventions to improve compliance with appointment keeping for medical services. Journal of the American Medical Association, 267, 1813-1817.
16. Wolosin, R.J. (1990). Effect of appointment scheduling and reminder postcards on adherence to mammography recommendations. Journal of Family Practice, 30, 542-547.

17. McDowell, I., Newell, C., & Rosser, W. (1989). Computerized reminders to encourage cervical screening in family practice. Journal of Family Practice, 28, 420-424.
18. Pierce, M., Lundy, S., Palanisamy, A., Winning, S., & King, J. (1989). Prospective randomized controlled trial of methods of call and recall for cervical cytology screening. British Medical Journal, 299, 160-162.
19. Rimer, B.K., Trock, B., Engstrom, P.F., Lerman, C., & King, E. (1991). Why do some women get regular mammograms? American Journal of Preventive Medicine, 7, 69-74.
20. King, E.S., Rimer, B.K., Trock, B., Balshem, B.A., & Enstrom, P. (1990). How valid are mammography self-reports? American Journal of Public Health, 80, 1386-1388.
21. Degnan, D., Harris, R., Ranney, J., Quade, D., Earp, J.A., & Gonzalez, J. (1992). Measuring the use of mammography: Two methods compared. American Journal of Public Health, 82, 1386-1388.
22. Hosmer, D.W., & Lemeshow, S. (1989). Applied logistic regression. NY: Wiley.

APPENDIX A

Standard Mammography Facility Reminder Letter



Scripps Memorial Hospitals

**The Lybrand Mammography
and Education Center**

9888 Genesee Avenue
Post Office Box 28
La Jolla, California 92038-0028

(619) 626-6224
(619) 626-6261 FAX

September 30, 1997

Recommended month for next mammogram: October, 1997

Dear Ms. :

Your last mammogram at The Lybrand Mammography and Education Center was approximately one year ago. For women in your age category, the American Cancer Society recommends routine screening mammography each year, along with yearly clinical breast exam and monthly breast self-examination. Currently, you are due for your annual mammogram.

Please call your personal physician at your earliest convenience to obtain a referral for your next mammogram. You also should make an appointment with him/her for your annual clinical breast exam.

We look forward to seeing you.

Sincerely,

The Lybrand Mammography and Education Center
(619) 626-6224

APPENDIX B

Physician Endorsement Reminder Letter

ROBERT P. BROUILLARD, M.D., F.A.C.P.

9850 Genesee Avenue, Suite 830
La Jolla, CA 92037
Telephone (619) 552-1410

Internal Medicine
Hematology and Oncology

September 30, 1997

Recommended month for next mammogram: October, 1997

Dear Ms. :

Your last mammogram at The Lybrand Mammography and Education Center was approximately one year ago. For women in your age category, the American Cancer Society recommends routine screening mammography each year, along with yearly clinical breast exam and monthly breast self-examination. Currently, you are due for your annual mammogram.

Please call me at 552-1410 at your earliest convenience to schedule an appointment for your annual clinical breast exam and to receive your mammography referral. Once you obtain your referral, call The Lybrand Mammography and Education Center at 626-6224 to make an appointment for your annual mammogram.

I look forward to seeing you.

Sincerely,



Robert P. Brouillard, M.D., F.A.C.P.

APPENDIX C
Telephone Survey

PICTURE OF HEALTH MAMMOGRAPHY PROJECT TELEPHONE INTERVIEW

Hello, my name is _____, with the Picture of Health Mammography Project. May I speak with _____? Hello _____, this is _____ of the Picture of Health Project. When you had your last appointment at _____ you signed a letter of consent to participate in our study; one part of the study is this telephone interview. At this time we would like to ask you some questions regarding mammography and breast cancer, in general. I expect this telephone interview to take about 15 - 20 minutes. Is this a good time for you to answer these questions?

(If not, ask if there is a better time to call. Thank the subject for her time and let her know we will call her back at the convenient time she specified).

Before I begin to ask you the questions, I would like to confirm that you have never had breast cancer -- for this study we are focusing only on women who have never had breast cancer. Have you had breast cancer?

(If yes, thank woman for her time, politely end interview)

O.K., then let's get started. As you answer, remember that we just want you to answer openly; there are no right or wrong answers.

Provider Variables - DO NOT READ QUESTION HEADINGS

- 1. Is there a particular doctor's office, clinic, health center or other place that you usually go to if you are sick or need advice about your health?**

1=yes

2=no (GO TO QUESTION #3)

8=don't know (GO TO QUESTION #3)

2. **What kind of place is it - a doctor's office, a hospital, a clinic, a health center or some other place? (CHECK ONLY ONE)**

01=doctor's office (private office or group practice)

02=hospital emergency room

03=hospital outpatient clinic

04=health center

private health clinic

private neighborhood health clinic

05=public health clinic

06=HMO/prepaid group practice, "group health"

07=Kaiser facility

08=Cigna health plan facility

09=PPO; preferred provider organization

10=medical facility (type not listed above)

3. **Our records show that Dr. _____ referred you for your most recent mammogram. Is he/she your regular doctor?**

1=yes

2=no

4. **What type of doctor is he/she?**

1=family or general practice

2=internist

3=gynecologist

4=other

8=don't know

5. **Are you presently covered by any of the following kinds of health insurance? ARE YOU COVERED BY...?**

(READ LIST AND RECORD A RESPONSE FOR EACH ITEM):

A. Commercial insurance, like Blue Cross, Prudential, or Medigap?

1=yes

2=no

8=don't know

B. A Health Maintenance Organization (HMO) or Individual Practice Association (IPA) like Kaiser or Maxicare?

1=yes

2=no

8=don't know

C. Preferred Provider Option?

1=yes

2=no

8=don't know

D. Medicare?

1=yes

2=no

8=don't know

E. Medical?

1=yes

2=no

8=don't know

F. Secure Horizons?

1=yes

2=no

8=don't know

G. Any other health insurance?

1=yes, specify: _____

2=no

8=don't know

Health History

6. **Has a doctor ever told you that you had a lump or tumor in your breast or breasts?**

1=yes

2=no

7. **Have you ever had a biopsy of your breast, in which a small segment of tissue was removed or a needle was used to extract fluid?**

1=yes

2=no (GO TO QUESTION #9)

8=don't know (GO TO QUESTION # 9)

8. **Did you have a surgical biopsy where a small segment of tissue was removed or was a needle used to extract fluid?**

1=surgical biopsy

2=needle aspiration biopsy

8=don't know

9. Is there a history of breast cancer in any one of the following members of your family? Remember we are talking only about breast cancer. (READ):

A. your mother?

1=yes

2=no

8=don't know

B. any sister?

1=yes

2=no

8=don't know

C. any grandmother?

1=yes

2=no

8=don't know

D. any aunt?

1=yes

2=no

8=don't know

E. any daughter?

1=yes

2=no

8=don't know OR

F. any granddaughter?

1=yes

2=no

8=don't know

10. Have you ever been told by a doctor that you have fibrocystic breasts, a condition that is not cancer but that makes your breasts feel lumpy or sore most of the time?

1=yes

2=no

8=don't know

Breast Cancer Screening History

11. Prior to your recent mammogram, had you ever had a mammogram before?

1=yes

2=no (GO TO QUESTION #17)

12. Including the last one, how many mammograms have you ever had? _____
(IF WOMAN CANNOT GIVE AN EXACT NUMBER, ASK FOR AN ESTIMATE)

13. Prior to the mammogram you had in the past few weeks, when was the mammogram you had before that?

- 1=less than 1 year
- 2=over 1 year ago
- 3=over 2 years ago
- 4=over 3 years ago
- 5=over 4 years ago
- 6=over 5 years ago
- 7=6 - 10 years ago
- 8=more than 10 years ago
- 9=don't know

14. Why did you have that mammogram...because you had a breast problem or for a routine check-up, that is, you did not have any symptoms (problems)?

- 1=had a breast problem
- 2=routine check-up

15. Have you ever had a mammogram where the results were NOT normal or the results were inconclusive?

- 1=yes
- 2=no (GO TO QUESTION #17)
- 8=don't know (GO TO QUESTION #17)

16. What happened as a result of the mammogram with abnormal or inconclusive results?

- 1=had a second mammogram
 - 2=had a biopsy (negative)
 - 3=other/specify: _____
-

17. How would you describe your pattern of having routine mammograms?
(READ LIST):

- 1=have had only one or have them sporadically (GO TO QUESTION #18)
- 2=have had them every 2-3 years on a regular basis (GO TO QUESTION #18), OR
- 3=have them annually (GO TO QUESTION #19) ?

18. I'm going to mention several reasons that may explain why you do not have annual mammograms. Please tell me how much each reason applies to you. Your options are: applies to you a great deal, applies somewhat, or does not apply at all. The first reason is... (READ OPTIONS):

A. "my doctor doesn't recommend it annually"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

B. "someone other than my doctor recommended against annual mammograms"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

C. "I'm concerned about radiation"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

D. "the exam is painful"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

E. "there are financial reasons, cost, my insurance does not cover it at all or not annually"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

F. "it's not necessary, I have no problems, all previous exams have been fine"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

G. "I don't think about it"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

H. "I'm too busy"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

I. "I have no family history of breast cancer"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

J. "I procrastinate"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

K. "I do not think it is important"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

L. "thinking about mammography makes me anxious"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

M. "I fear that they'll find something"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

N. "I'm embarrassed"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

O. "I don't have transportation"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

P. "I'm in poor health"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

Q. Are there any other reasons? (SPECIFY): _____

19. **I'm going to mention several reasons that may explain why you have annual mammograms. Please tell me how much each reason applies to you. Your options are: applies to you a great deal, applies somewhat, or does not apply at all. The first response is... (READ OPTIONS):**

A. "my doctor recommends it"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

B. "organizations such as the American Cancer Society recommend it"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

C. "my friends, family, others recommend it"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

D. "it is effective in detecting cancer early"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

E. "I want peace of mind"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

F. "it is convenient"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

G. "I have a family history of breast cancer"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

H. "I'm afraid I'll develop breast cancer"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

I. "I have a history of benign breast problems (cysts, etc.)"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

J. "it's the sensible thing to do"

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

K. Are there any other reasons? (SPECIFY): _____

20. **I want you to think about the mammogram you had most recently. When the mammography equipment was pressing against your breasts during the X-ray, how did you feel? (READ):**

1=no physical discomfort

2=slight physical discomfort

3=moderate physical discomfort

4=substantial physical discomfort OR

5=extreme physical discomfort ?

- 21. A physical breast examination is when the breast is felt for lumps by a doctor or other health professional. Have you ever had a physical breast examination?**

1=yes

2=no (GO TO QUESTION #24)

8=don't know (GO TO QUESTION #24)

- 22. When did you have your last physical breast examination?**

1=less than 1 year

2=over 1 year ago

3=over 2 years ago

4=over 3 years ago

5=over 4 years ago

6=over 5 years ago

7=6 - 10 years ago

8=more than 10 years ago

9=don't know

- 23. Why did you have your last physical breast exam...Because you had a breast problem or for a routine check-up, that is you did not have any symptoms (problems)?**

1=had a breast problem

2=routine check-up

- 24. Do you examine your own breasts for lumps or other changes?**

1=yes

2=no (GO TO QUESTION #26)

8=don't know (GO TO QUESTION #26)

- 25. How often do you examine your breasts?**

_____ times per

day

week

month

year

other/specify: _____

88=don't know

Knowledge/Beliefs

- 26. How often is routine mammography recommended for women in your age range (50 and older) by experts such as the American Cancer Society?**

1=never

2=every 2 -5 years

3=annually

4=once

5=only when there's a problem

6=other/specify: _____

8=don't know

- 27. What proportion of women do you think will get breast cancer at some time during their lives? Do you think it is...(READ CHOICES):**

1=1 in 4

2=1 in 8

3=1 in 25, OR

4=1 in 50 ?

8=don't know (DO NOT READ THIS ALTERNATIVE)

- 28. What are your chances of getting breast cancer sometime during your lifetime? Do you think it is...(READ CHOICES):**

1=1 in 4

2=1 in 8

3=1 in 25, OR

4=1 in 50 ?

8=don't know (DO NOT READ THIS ALTERNATIVE)

- 29. Are women 50 years and older more likely, less likely, or equally likely to get breast cancer than women younger than 50?**

1=more likely

2=less likely

3=equally likely

4=other/specify: _____

8=don't know

Intentions

30. **What is the likelihood that you will have another routine screening mammogram next year, even if your doctor does not suggest one? Is it...(READ):**

1=very unlikely
2=somewhat unlikely
3=a 50/50 chance
4=somewhat likely, OR
5=very likely ?

31. **If your doctor recommends one, what is the likelihood that you will have another routine screening mammogram next year? Is it...(READ):**

1=very unlikely
2=somewhat unlikely
3=a 50/50 chance
4=somewhat likely, OR
5=very likely ?

Efficacy and Outcome Expectations

32. **How confident are you that you will be able to schedule a mammogram appointment in the next 12 months (i.e., phone for an appointment, schedule it at a convenient time, etc.)? Are you...(READ):**

1=not at all confident
2=slightly confident
3=somewhat confident
4=fairly confident, OR
5=very confident ?

33. **How confident are you that you will be able to complete the appointment once it is scheduled (i.e., drive yourself or obtain transportation, get the money and/or insurance to pay for the mammogram, etc.)? Are you...(READ):**

1=not at all confident
2=slightly confident
3=somewhat confident
4=fairly confident, OR
5=very confident ?

- 34. How confident are you that having annual mammograms will improve your chances of survival if you have breast cancer? Are you...(READ):**

1=not at all confident
2=slightly confident
3=somewhat confident
4=fairly confident , OR
5=very confident ?

Recent Mammography Experience

For the next 3 questions, I want you to think again about your most recent mammogram experience. Please answer these questions openly; your answers will not be shared with mammography facility staff. I will read a statement, and I'd like you to tell me how much you agree or disagree with it...(READ):

- 35. "I was very satisfied with the care I received."
Do you (READ):**

1=strongly disagree
2=disagree
3=neutral
4=agree, OR
5=strongly agree ?

- 36. "I feel confident that the mammogram was taken properly."
Do you (READ):**

1=strongly disagree
2=disagree
3=neutral
4=agree, OR
5=strongly agree ?

- 37. "The person was too rough when taking the mammogram."
Do you (READ):**

1=strongly disagree
2=disagree
3=neutral
4=agree, OR
5=strongly agree ?

Demographic Information

- 38. In what month and year were you born?**

(date: month __ , year __)

- 39. What was the highest level of education that you completed?**

1=less than eighth grade
2=8th grade to 11th grade
3=high school graduate
4=post high school, trade or technical school
5=1 -3 years of college
6=college graduate
7=some graduate work or graduate degree

- 40. Which of the following best describes your ethnic or racial group? (READ):**

1=white, or Caucasian, not of Hispanic origin
2=Mexican American, Mexican/Mexicano, Hispanic, Puerto Rican, Cuban, Chicano,
other Latin American, or other Spanish
3=African American
4=American Indian
5=Asian
6=Pacific Islander
7=other/specify: _____

- 41. What is your present marital status?**

1=married or living as married
2=widowed
3=divorced
4=separated
5=never married

- 42. What is your current employment status?**

1=working at a full-time job
2=working at a part-time job
3=not working, but looking for work
4=a full-time homemaker
5=a non-salaried volunteer
6=retired
7=unable to work due to disability
8=other/specify: _____

43. Please stop me when I get to the category that best describes your family's total annual income. Is it... (READ):

1=less than \$10,000

2=10,001 to 15,000

3=15,001 to 20,000

4=20,001 to 25,000

5=25,001 to 30,000

6=30,001 to 40,000

7=40,001 to 50,000

8=50,001 and over

9=don't know (DO NOT READ THIS OPTION)

10=refused (DO NOT READ THIS OPTION)

WE ARE NOW FINISHED WITH THE TELEPHONE INTERVIEW. ON BEHALF OF THE PICTURE OF HEALTH STAFF, I'D LIKE TO THANK YOU FOR YOUR TIME AND INTEREST IN THE STUDY. YOUR INPUT IS VERY VALUABLE TO US.

HAVE A GOOD DAY/EVENING...